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09/868,732	11/01/2001	Leif Andersson	4951US	6509

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary****Application No.**

09/868,732

**Applicant(s)**

ANDERSSON ET AL.

**Examiner**

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 24-40 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 and 24-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 36-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Action is in response to the communication filed on 6/8/2005. Applicant's arguments are addressed on a per section basis. The amendment filed 6/8/2005 is acknowledged. The amendment has been entered. Claims 1-17 and 24-40 are currently pending in the application and are addressed herein.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

### ***Election/Restrictions***

Claims 10-17 and 24-35 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/23/2004.

Claims 1-9 and 36-40 are examined herein.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 36-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a method for selecting an animal having desired genotypic properties wherein the method comprises testing the animal for the presence of a parentally imprinted quantitative trait locus (QTL), and includes (1) selecting pigs wherein the QTL maps to about position 2p1.7, (2) the QTL being related to the muscle mass and/or fat deposit of the animal, (3) the QTL comprising at least a part of an IGF-2 gene, (4) the QTL comprising a marker characterized as nt241(G-A) or as Swc9, (5) the paternal or maternal allele of the QTL being predominantly expressed in the animal, (6) testing a nucleic acid comprising a fragment of a QTL, and (7) the animal comprises a breeding animal or animal destined for slaughter.

Therefore, the broadest claims encompass a method of testing any animal for the presence of a parentally imprinted QTL (or a fragment of the QTL) wherein the QTL can be associated with any desired genetic property. As such, the claims encompass a method for identifying a genus of QTLs wherein each species of the genus can have a different structure and different function. For instance, the QTLs encompassed by the claims include QTLs which comprise different nucleotide sequences (e.g., different polymorphisms, alleles of different genes) which can be associated with different phenotypes (e.g., muscle mass, fat deposit or any other desired phenotypic trait). Therefore, the claims encompass a genus of indeterminate size, but which could easily encompass millions of different QTLs, including QTLs which are structurally and functionally unrelated to each other and QTLs which have yet to be identified.

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To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a parentally imprinted QTL whose presence can be used to identify an animal having a desired genotypic property. The specification does not identify any particular sequence structure or particular function which must be conserved among all members of the genus, nor does the specification explicitly describe any particular QTL functional fragments. Furthermore, the prior art does not appear to teach any parentally imprinted QTLs. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states, “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required.

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See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the only parentally imprinted QTL associated with a desired genotypic property is the paternally imprinted QTL comprising the IGF-2 gene and a marker characterized as nt241(G-A) or as Swc9, wherein the QTL is associated with fat deposit in pigs. There is insufficient written description of the broad genus of QTLs encompassed by the claims.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claims 1-9 and 36-40 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for identifying a porcine having a paternally imprinted QTL wherein the method comprises identifying the presence of the IGF-2 gene having the nt241(G-A) polymorphism in the genome of said porcine using the specific oligonucleotides used to identify the QTL in the working example (e.g., the IGF-2nt245(G-A) specific primer and the SWC9 primer) wherein said IGF-2 gene co-localizes with the SWC9 microsatellite marker and wherein the presence of said QTL is correlated with decreased fat deposit in said porcine;

does not reasonably provide enablement for the full breadth of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

*Wands* states on page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

#### The nature of the invention

The instant claims are drawn to method for selecting an animal for having desired genotypic properties comprising testing said animal for the presence of a parentally imprinted quantitative trait locus (QTL). Therefore, the nature of the invention is a method of identifying an animal which has a desired genetic trait wherein the animal can be used to produce offspring that have the desired phenotypic trait.

#### The breadth of the claims

The claims are very broad and encompass identifying an animal having any parentally imprinted QTL wherein the QTL can be associated with any desired genotypic property and wherein the QTL is correlated to a phenotypic effect in any type of animal, including animals of different species. Additionally, the claims encompass a functional fragment of a QTL. As indicated above the claims encompass a genus of QTLs that includes possibly millions of different QTLs including QTLs that are structurally and functionally unrelated to each other.

The unpredictability of the art and the state of the prior art

The prior art does not appear to teach any parentally imprinted QTLs, considering that parental imprinting is defined as a phenomenon wherein the imprinted trait of one parent is preferably but gender-aspecifically expressed in his or her offspring. The phenomenon of parental imprinting gives rise to differential expression of paternally and maternally inherited alleles of certain genes due to sex-specific epigenetic differences inherited from the germline, which is different from allelic “dominance” where a dominant allele affects the phenotype regardless if the animals are homozygous or heterozygous for the dominate allele and irrespective to maternal or paternal inheritance of the allele. It is noted that Applicants acknowledge this difference between dominance and parental imprinting in the communication filed 6/8/2005 (e.g., see page 13, first two paragraphs).

The prior art teaches that identification of a QTL associated with a particular phenotype in one species of animal is not indicative that the QTL will be correlated to the same phenotype in all species. For instance, **Pandya et al. (American Journal of Human Genetics 1994)** teaches that although IGF-1 and IGF-2 (as well as there respective receptors) have been associated with body size in mice, there is “no evidence that the IGF-1 locus is imprinted in man”. Therefore, the prior art teaches that the identification of a correlation of a phenotype and a QTL in one species does not indicate that there is a correlation between the phenotype and QTL in all species of animals.

The prior art also indicates that a single amino acid substitution in a polypeptide can greatly alter the function of the polypeptide. Specifically, **Witkowski et al. (Biochem. 1999, 38:11643-11650)** teaches that a single amino acid substitution of an active site cysteine with



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glutamine changes a beta-ketoacyl synthase to a malonyl decarboxylase (e.g., see abstract, and Table 1 on page 11647). Therefore the prior art teaches that genetic alterations, even at the single amino acid level can change the function of a molecule. Therefore, the only specific polymorphism of the IGF-2 gene which can be correlated to fat deposit is the specific nt241(G-A) polymorphism of the porcine IGF-2 gene.

#### Working Examples and Guidance in the Specification

The specification has identified one specific paternally imprinted QTL which is correlated to decreased fat deposit in pigs, that QTL being the QTL comprising the porcine IGF-2 gene having the nt245(G-A) polymorphism wherein the QTL co-localizes with the SWC9 microsatellite marker. Therefore, the only method of identifying an animal having a desired genotypic property that is disclosed by the specification is a method for selecting a porcine having a paternally imprinted QTL wherein the QTL comprises the IGF-2 gene having the nt241(G-A) polymorphism and which co-localizes with the SWC9 microsatellite marker, wherein the presence of the QTL is correlated with decreased fat deposit in pigs.

#### Quantity of Experimentation

Considering the vast number of QTLs encompassed by the claims, an enormous amount of additional experimentation would be required in order for one of skill in the art to be able to make and use the full scope of the claimed invention. For instance, one would have to identify parentally imprinted QTLs having a correlation to a desired genotypic property. Considering every possible QTL and desired genotypic property encompassed by the claims, this would be a daunting effort.

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The art also teaches that although a genetic element (i.e. QTL) may be associated with a particular effect in one species of animal, does not necessarily indicate the same genetic element will be associated with the same effect in all species of animals. Also, the art indicates that a single genetic alteration in a gene can alter the function of that gene. Therefore, additional experimentation would have to be done in order to overcome these art-recognized problems.

#### Level of the skill in the art

The level of the skill in the art is deemed to be high.

#### Conclusion

Considering the nature of the invention, the breadth of the claims, the unpredictable nature of the invention as recognized in the prior art, the limited amount of working examples and guidance provided, and the high degree of skill required to practice the invention, it is concluded that the specification does not provide an enabling disclosure for the full scope of instant claims. Therefore, additional experimentation is required before one of skill in the art could make and use the claimed invention. The amount of additional experimentation required to perform the broadly claimed invention is undue.

#### ***Response to Arguments***

Applicant's arguments filed 6/8/2005 have been fully considered. With respect to the objection to the specification and the rejection of claims under 35 USC 112, 2<sup>nd</sup> paragraph and 35 USC 102, Applicants arguments in view of the amendments are persuasive and the objection/rejections are withdrawn. With respect to the rejection of claims under 35 USC 112,

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1<sup>st</sup> paragraph, Applicants arguments filed 6/8/2005 have been fully considered but they are not persuasive.

With respect to the written description rejection, Applicants argue that the specification discloses the claimed method and points out the specific location in the specification where support for the claims can be found (e.g., see pages 9-11 of the communication filed 6/8/2005). Therefore, Applicants contend that one of ordinary skill in the art would conclude that the Applicants were in possession of the claimed invention.

In response, it is respectfully pointed out that rejection is based on the breadth of the claims. Specifically, the claims encompass identifying any parentally imprinted QTL. However, Applicants have not provided a sufficient written description of the parentally imprinted QTLs encompassed by the claims because the specification has only described one specific parentally imprinted QTL, the paternally imprinted QTL that is the polymorphism of the porcine IGF-2 gene having the nt241(G-A) alteration. Since the claims encompass identifying any parentally imprinted QTL (i.e. any maternally or paternally imprinted QTL) in any species of animal, the description of a single paternally imprinted QTL in porcine is not sufficient to describe the broad genus of parentally imprinted QTLs encompassed by the claims. Therefore, Applicants' arguments are not persuasive and the rejection is not withdrawn.

With respect to the scope of enablement rejection, Applicants argue that the M.P.E.P. indicates that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied (citing M.P.E.P. 2164.01(b)). Applicants

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argue that in light of the specification, one of skill in the art would be able to make and use the method of claim 1 without undue experimentation. Applicants specifically point out that the specification has disclosed and taught how to identify the parentally imprinted QTL on chromosome 2 at 2p1.7 (e.g., see pages 11-12 of the communication filed 6/8/2005).

In response, it is respectfully pointed out that the Examiner has acknowledged that the specification has provided an enabling disclosure for identifying a porcine having a paternally imprinted QTL wherein the method comprises identifying the presence of the IGF-2 gene having the nt241(G-A) polymorphism in the genome of said porcine (i.e., the 2p1.7 QTL) wherein the presence of said QTL is correlated with decreased fat deposit in said porcine. However, the claims are very broad and encompass identifying any parentally imprinted QTL in any species of animal. Considering that no other parentally imprinted QTLs could be identified in the prior art and considering that the prior art explicitly teaches that identification of a QTL associated with a particular phenotype in one species of animal is not indicative that the QTL will be correlated to the same phenotype in all species (e.g., Pandya et al. as indicated above) an undue amount of additional experimentation would be required in order for one of skill in the art to be able to make and use the claimed invention to its full scope. Therefore, the method disclosed in the specification does not bear a reasonable correlation to the entire scope of the claim, thus the enablement requirement of 35 U.S.C. 112 is not satisfied.

It is noted that amending the claims such that they are limited in scope to that which is identified as being enabled (i.e., see above) would obviate this rejection.

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***Conclusion***

**No claim is allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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